

Serial No. 10/021,694

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Remarks

Claims 1-25 are pending in the present application. Claims 1-25 have been rejected. By the present amendment, claim 1 has been amended and new claim 26 has been added.

***Rejection under 35 U.S.C. §102(b)***

Initially, in the Office Action of December 9, 2003, claims 1-23 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,298,569 to Read, which patent teaches an indicator that is designed to undergo a color change when exposed to steam-formaldehyde sterilization. The indicator comprises a substrate carrying a dye such as Congo red, Naphthalene black 10B, or Benzo purpurin, which dye changes color under steam-formaldehyde sterilizing conditions. The indicator can also contain one or more additional dyes which do not change color during sterilization and which are chosen to enhance the color change of the indicator, such as Irgacet blue 2 GLN or Methylene blue.

The present invention is directed to a chemical indicator ink for steam-formaldehyde sterilization processes. In accordance with one embodiment, the chemical indicator ink contains at least one primary organic dye selected from the group consisting of Congo red, Benzo purpurin B, Chicago sky blue 6B, Direct red 75, Evans blue, Naphthol blue black, Nitro red, and combinations thereof. The organic dyes will undergo an irreversible color change when exposed to formaldehyde in the presence of steam. Moreover, the organic dyes will not undergo a color change when exposed to other sterilization processes such as ethylene oxide gas, high-temperature steam, dry heat, or combinations thereof. The chemical indicator ink of the present invention can further contain at least one secondary organic dye that enhances the color change of the chemical indicator ink and does not undergo a color change when exposed to formaldehyde vapor in the presence of steam. The at least one secondary organic dye

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can be selected from the group consisting of methylene blue, trypan blue, direct blue 71, and combinations thereof.

Claim 1 is amended herein and now recites a chemical indicator ink for steam-formaldehyde sterilization processes containing at least one primary organic dye selected from the group consisting of Chicago sky blue 6B, Direct red 75, Evans blue, Naphthol blue black, Nitro red, and combinations thereof. In addition, new claim 26 is added herein which recites the chemical indicator ink of claim 1 further containing at least one primary organic dye selected from the group consisting of Congo red, Benzo purpurin B, and combinations thereof. These primary organic dyes are described on pages 2 and 4-8 of the specification and are within the scope of the original claim set. Accordingly, no new matter has been added.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. In contrast to amended claim 1, Read teaches that the dye that will undergo a color change when exposed to formaldehyde vapor in the presence of low temperature steam is Congo red, Naphthalene black 10B, or Benzo purpurin. None of these dyes read on the subject matter of amended claim 1. Moreover, Congo red and Benzo purpurin, the dyes recited in new dependent claim 26, are provided in combination with either Chicago sky blue 6B, Direct red 75, Evans blue, Naphthol blue black, Nitro red, or combinations thereof. As such, Read does not teach or suggest the invention recited in independent claim 1 as amended herein, or new dependent claim 26. Rejected claims 2-23 contain all of the limitations of the base claim to which they depend. Accordingly, applicant submits that Read does not anticipate the present application as amended herein and respectfully requests that the rejection be withdrawn.

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***Rejection under 35 U.S.C. §103(a)***

Also in the Office Action, claims 24 and 25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Read in view of U.S. Patent No. 5,258,0654 to Fujisawa. In support of the instant rejection, the Examiner asserted that although Read differs from the present invention in that there is no disclosure of a preservative in the indicator composition, Fujisawa notes that preservatives are conventionally incorporated into ink compositions for sterilization indicators, and sorbic acid is a commonly used preservative in these applications. The Examiner concluded that it would have been obvious to one of ordinary skill in the art to incorporate a preservative into the indicator composition of Read to allow the composition to be more storage stable and maintain the integrity of the components.

In order to “support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” MPEP 2142 (citing *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)). In view of the present amendment, applicant submits that the Examiner has not met this burden and respectfully requests that the rejection be withdrawn.

In order to establish a *prima facie* case of obviousness, *inter alia*, all of the claimed limitations must be taught or suggested by the prior art. MPEP 2143.03 (citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). As noted above, claim 1 is amended herein and recites a chemical indicator ink for steam-formaldehyde sterilization processes containing at least one primary organic dye selected from the group consisting of Chicago sky blue 6B, Direct red 75, Evans blue, Naphthol blue black, Nitro red, and combinations thereof. Neither Read nor Fujisawa can be relied upon in support of the instant rejection, as neither reference teaches nor suggests all of the claimed limitations. More specifically, neither Read nor Fujisawa teach or suggest a

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chemical indicator ink for steam-formaldehyde sterilization processes containing at least one primary organic dye selected from the group consisting of Chicago sky blue 6B, Direct red 75, Evans blue, Naphthol blue black, Nitro red, and combinations thereof. Claims 2-25 and new claim 26 contain all of the limitations of the base claim from which they depend. Accordingly, for all of the reasons set forth above, applicant submits that the Examiner has not presented a *prima facie* case of obviousness and respectfully requests that the rejection be withdrawn.

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Conclusion

Applicant respectfully submits that, in view of the above amendments and remarks, the application is in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,  
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